



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 27, 2015

Kuraray Noritake Dental Inc.
C/O Mr. Goro Asanuma
Kuraray America, Inc.
33 Maiden Lane, 6th Floor
New York, New York 10038

Re: K142625

Trade/Device Name: PANAVIA SA Cement Plus Automix
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental cement
Regulatory Class: II
Product Code: EMA
Dated: December 22, 2014
Received: December 23, 2014

Dear Mr. Asanuma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Tina
Kiang -S

for Erin I. Keith, M.S.

Director

Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K142625

Device Name: PANAVIA SA Cement Plus Automix

Indications for Use:

- [1] Cementation of crowns, bridges, inlays and onlays
- [2] Cementation of prosthetic restorations on implant abutments and frames
- [3] Cementation of adhesion bridges and splints
- [4] Cementation of posts and cores
- [5] Amalgam bonding

Prescription Use ✓ AND/OR Over-The-Counter Use N/A
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Date: January 27th, 2015

510(k) Summary

3-1. 510(k) owner (submitter)

- | | |
|-------------------------|---|
| 1) Name | Kuraray Noritake Dental Inc. |
| 2) Address | 1621 Sakazu, Kurashiki, Okayama 710-0801, Japan |
| 3) Contact person | Michio Takigawa
Quality Assurance Department |
| 4) Contact person in US | Goro Asanuma
KURARAY AMERICA, INC.
33 Maiden Lane, 6th Floor, New York, NY 10038
Tel: (212)-986-2230 (Ext. 115) or (800)-879-1676
Fax: (212)-867-3543 |

3-2. Name of Device

- | | |
|-----------------------------|---|
| 1) Trade / Proprietary name | PANAVIA SA Cement Plus Automix |
| 2) Classification name | Dental cement
(21 CFR section 872.3275. Product code: EMA) |
| 3) Common name | Dental adhesive resin cement |

3-3. Predicate devices

- | | |
|------------------------------|--|
| 1) PANAVIA SA CEMENT Automix | 510(k) Number: K120379
Classification: Dental cement
Product Code: EMA
21 CFR Section: 872.3275
Applicant: Kuraray Noritake Dental Inc. |
| 2) PANAVIA F 2.0 | 510(k) Number: K032455
Classification: Dental cement
Product Code: EMA
21 CFR Section: 872.3275
Applicant: Kuraray Noritake Dental Inc. |
| 3) CLEARFIL AP-X | 510(k) Number: K012740
Classification: Tooth shade resin material
Product Code: EBF
21 CFR Section: 872.3690
Applicant: Kuraray Noritake Dental Inc. |
| 4) CLEARFIL TRI-S BOND | 510(k) Number: K042913
Classification: Resin tooth bonding agent
Product Code: KLE
21 CFR Section: 872.3200
Applicant: Kuraray Noritake Dental Inc. |
| 5) CLEARFIL DC CORE PLUS | 510(k) Number: K111982
Classification: Tooth shade resin material
Product Code: EBF
21 CFR Section: 872.3690
Applicant: Kuraray Noritake Dental Inc. |

3-4. Device Description

The subject device is a dual-cure (light- and/or self-cure), fluoride releasing, radiopaque self-adhesive resin cement for ceramic (porcelain, lithium disilicate, zirconia, etc.), composite resin, and metal restorations. It is supplied in an automix delivery system which can mix equal amounts of two components.

This is the new registration application for the subject device and there have not been any prior submissions regarding the subject device.

3-5. Statement of Intended Use

The subject device is indicated for the following uses:

- [1] Cementation of crowns, bridges, inlays and onlays
- [2] Cementation of prosthetic restorations on implant abutments and frames
- [3] Cementation of adhesion bridges and splints
- [4] Cementation of posts and cores
- [5] Amalgam bonding

3-6. Substantial Equivalence Discussion

1) Intended uses

Intended uses of the subject device and predicate devices, PANAVIA SA CEMENT Automix which is self-adhesive resin cement and PANAVIA F2.0 which is dental resin cement, are as listed on the following table.

	Trade name	Intended use
Subject device	PANAVIA SA Cement Plus Automix	[1] Cementation of crowns, bridges, inlays and onlays [2] Cementation of prosthetic restorations on implant abutments and frames [3] Cementation of adhesion bridges and splints [4] Cementation of posts and cores [5] Amalgam bonding
Predicate devices	PANAVIA SA CEMENT Automix	[1] Cementation of crowns, bridges, inlays and onlays made of porcelain, ceramic, composite resin or metal [2] Cementation of porcelain, ceramic, composite resin or metal restorations on implant abutments [3] Cementation of metal cores, resin cores, metal posts or glass fiber posts
	PANAVIA F2.0	[1] Cementation of metal crowns and bridges, inlays and onlays [2] Cementation of porcelain crowns, inlays, onlays and veneers [3] Cementation of composite resin crowns, inlays, and onlays [4] Cementation of adhesion bridges [5] Cementation of endodontic cores and prefabricated posts [6] Amalgam bonding

The intended use of the subject device was written up based on those of the predicate devices. The implant abutments and frames are made of the same materials. Their required adhesive performance is same. The adhesion bridges and splints are also made of the same materials. Their required adhesive performance is same, too.

Therefore, the intended use of the subject device is substantially equivalent to those of the predicate devices.

2) Chemical ingredients/ Safety

Except for 5 chemical ingredients, all ingredients in the subject device have been used in the predicate devices. Regarding the predicate devices, there have not been any reported problems or recalls according to the post market adverse event reporting requirements in the US.

The subject device contains new 5 ingredients. Therefore, we evaluated the subject device referring to ISO 10993 series and ISO 7405. As a result of the tests, it was concluded that the subject device is substantially equivalent in biological safety to the predicate device.

3) Technological characteristics/ Effectiveness and Performance

Physical and mechanical properties of the subject device were evaluated according to ISO 4049: 2009 (Dentistry - Polymer-based restorative and materials).

The results of comparative study performed according to ISO 4049: 2009 were indicated below.

Section	PANAVIA SA Cement Plus Automix (Subject device)		PANAVIA SA CEMENT Automix (Predicate device)	
	Shade type: Universal (A2)	Shade type : White	Shade type: Universal (A2)	Shade type : White
5.2.2 Film thickness, luting materials	COMPLIES	COMPLIES	COMPLIES	COMPLIES
5.2.4 Working time, Class 1 and Class 3 luting materials	COMPLIES	COMPLIES	COMPLIES	COMPLIES
5.2.6 Setting time, Class 3 materials	COMPLIES	COMPLIES	COMPLIES	COMPLIES
5.2.9 Flexural strength	COMPLIES	COMPLIES	COMPLIES	COMPLIES
5.2.10 Water sorption and solubility	Water sorption	COMPLIES	COMPLIES	COMPLIES
	Solubility	COMPLIES	COMPLIES	COMPLIES
5.4 Color stability after irradiation and water sorption	COMPLIES	COMPLIES	COMPLIES	COMPLIES
5.5 Radio-opacity	COMPLIES	COMPLIES	COMPLIES	COMPLIES

The results indicate that the subject device and the predicate device comply with the requirements of ISO 4049: 2009. From the above, it can be said that comparative study of the subject device is substantially equivalent to that of the predicate device.

The shear bond strengths for the substrates which are matched to each indication referring to ISO/TS 11405: 2003 were indicated below.

Adherend surface (Material composition)	Criteria	Shear bond strength	
		Subject device	Predicate device
Tooth dentin	In-house standard	COMPLIES	COMPLIES
Tooth enamel		COMPLIES	COMPLIES
Ceramic		COMPLIES	COMPLIES
Metal		COMPLIES	COMPLIES
Titan		COMPLIES	COMPLIES
Composite resin		COMPLIES	COMPLIES
Amalgam		COMPLIES	COMPLIES

The shear bond strengths to all substrates of the subject device were not statistically ($P>0.05$) different from those of the predicate devices.

Therefore, it was concluded that the bonding performance to all substrates of the subject device was equivalent to those of the predicate devices.

Released fluorine ion test was performed to validate the substantial equivalence of the subject device with the predicate device.

It was concluded that amount of released fluorine ion from the subject device is substantially equivalent to those from the predicate device.

3-7. Biocompatibility

The subject device is classified according to ISO 7405:2008 and ISO 10993-1:2009 as an external communicating device that will have permanent (> 30 days) contact with tissues. We performed the biological safety tests of the subject device. As a result of the tests, it was concluded that the subject device is substantially equivalent in biological safety to the predicate device.

3-8. Conclusion

The comparison for intended uses, chemical ingredients/ safety and performance data shows that the subject device is substantially equivalent to the predicate devices.

This submission information including the nonclinical testing provided supports that the subject device is as safe and as effective as the predicate devices.